## 23719

## IN THE U.S. PATENT AND TRADEMARK OFFICE

Inventor Walter SARSTEDT

Patent App. 10/593,171

Filed 15 September 2006 Conf. No. 8813

For BLOOD-COLLECTION DEVICE FOR NEWBORN BABIES AND

**INFANTS** 

Art Unit 3736 Examiner Pani, J

Hon. Commissioner of Patents

Box 1450 Appealed 10-Jun-11

Alexandria, VA 22313-1450

#### APPEAL BRIEF UNDER 37 CFR 41.37

Now comes appellant by his duly authorized attorney and submits his brief under the provisions of 37 CFR 41.37.

#### I. REAL PARTY IN INTEREST

The real party in interest here is Sarstedt AG & Co. of Germany as evidenced by the assignment recorded 21 July 2008 at reel 021262, frame 0137.

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## II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

#### III. STATUS OF CLAIMS

The application contains three claims numbered 1, 3, and 5. All are appealed. Claim 1 is the sole independent claim.

Submitted herewith is an Amendment On Appeal that fixes an obvious formal error in dependent claim 5. This is clearly not new matter or a new issue so entry of this amendment is in order.

The appealed claims are reproduced in the attached Claim Appendix.

#### IV. STATUS OF AMENDMENTS AFTER FINAL ACTION

A single amendment after final action was refused entry.

#### V. SUMMARY OF CLAIMED SUBJECT MATTER

Since the claims have been carefully drafted without legal jargon (e.g. 'said') and to be as succinct as possible, the invention will be described below in the words of the claims and with parenthetical references to the clean version of the specification as filed 10 November 2010 and drawing as filed 15 September 2006.

The invention is a blood-collecting device for newborn babies and infants. The device comprises:

a cannula 3 (spec. p. 3, 1. 3; FIGS. 1 and 2) extending along an axis and having at one axial end 4 (spec. p. 3, 1. 4; FIGS. 1 and 2) a blood inlet and at an opposite axial end 5 (spec. p. 3, 1. 6; FIGS. 1 and 2) a blood outlet;

a one-piece bow-shaped bridge element 6 (spec. p. 3, 1. 7; FIGS. 1 and 2) having a front end 2 in which the cannula 3 is fixed and a rear end through which the axis passes and defining with the front end a free space, the cannula outlet 5 being exposed between the front and rear ends in the free space and the inlet 4 being outside the free space; and

a grip part 7 (spec. p. 3, 1. 8; FIGS. 1 and 2) centered on the axis and fixed on the rear end of the bridge element 6 rearward of the rear end and outside the free space.

With this device it is possible to delicately introduce the tip 4 into a vein of a neonate and allow rotate the bow-shaped part 6 up so that blood can drip freely from the rear cannula end 5 into a vessel. Drawing blood from such a patient is very, very difficult and this device makes it much easier.

Claim 3 describes how the bridge element 6 is C-shaped as clearly shown in FIG. 1.

Claim 5 states that the grip part has an outer surface substantially symmetrical to the axis.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

# Rejection A:

Claim 5 was rejected under §112 for lack of antecedent basis of the term "handle." This problem is cured by the attached Amendment on Appeal.

#### Rejection B:

Claim 1 was rejected under §112 because the term "one piece" inserted with the First Amendment of 02 October 2010 had no support in the original specification. The attempt to delete this term, however, was considered to be introducing a new issue in the Advisory Action. Thus on the one hand, this term is new matter that cannot be introduced into the application, and on the other hand deleting it is a new issue and is not permissible.

## Rejection C:

Claim 5 is rejected under §112 for use of the term "symmetrical," since this word was not used in the original disclosure.

## Rejection D:

Claims 1, 3, and 5 are rejected under §103 on US 4,976,271 of Blair.

#### VII. ARGUMENTS

## Rejection A (claim 5, new matter for "handle" §112):

If the Amendment On Appeal is entered, this rejection is mooted.

# Rejection B (claim 1, "one piece" as new matter or issue §112):

Here if the term "one-piece" is new matter, it should not be permitted into the case and deleting it should have been allowed because deleting it would merely be eliminating something that should not be there, in which case the amendment after final should have been entered. If the term is not new matter, then deleting it is arguably a new issue and this term should be considered a valid restriction and considered with regard to patentability. This amendment was not entered so the examiner is implicitly admitting that the term is not new matter.

The examiner's position is however that it is new matter but that deleting it is a new issue.

Appellant herewith leaves resolution of this catch 22 to the Board. If the term is considered to be new matter, it will be deleted. If it is a not new matter and is a new issue and cannot be deleted, it must be left in and should be considered as part of the claim.

With respect to the position that "one-piece" is not supported by the original disclosure, it is noted that FIGS. 1 and 2 show the bridge 6 to be a smooth uninterrupted body from one end to the other and therefore inherently of one piece. No seam or structure implying anything other than one-piece construction is

shown or suggested, so the drawing, which is part of the original disclosure, clearly supports the "one-piece" limitation.

# Rejection C (claim 5, new matter for "symmetrical" §112:

FIGS. 1 and 2, which form part of the original disclosure of this application, clearly show the grip part 7 from two  $90^{\circ}$ -offset directions, and in both views the part 7 is identical. This is clear proof that the element is in fact symmetrical to the axis through its center so that the term "symmetrical," while not in the original disclosure is in fact supported by the original disclosure and not new matter.

# Rejection D (all claims, §103 on Blair):

Blair relates to a device that is differently constructed and is used differently. More particularly in the FIG. 8 embodiment referred to by the examiner a cartridge 3 or the like is inserted in a holder 11, but without a grip end axially aligned with the needle 1. Thus the inner end of the needle 1 is basically exposed, and the device could not be manipulated like the instant invention by a hand gripping the part 7 aligned with the needle. Instead the rear end 95 is a short protuberance that serves mainly to hold the cartridge 3 in place.

The invention of claim 1 of this application has the "bow-shaped" part that claim 3 goes on to describe as being C-shaped and that provides significant space for draining the rear needle end. Of course this is not needed in Blair where the goal is to fit the cartridge 3 to the needle 1.

The "symmetrical" feature of FIG. 5 is neither shown nor suggested by Blair. It also would not be a necessary or obvious

feature since in this structure the cannula extends off at an angle so the last thing the blood technician would do is rotate it. This makes it very easy for the user to aim and direct the pointed needle end, and to subsequently orient the bow-shaped bridge element out of the way so that the blood dripping from the rear needle end can be caught. Gripping the Blair system by the part 12 and rotating it as suggested by the examiner would not meet claim 1 since the rotation would be about the axis of the part 12 that is not the axis of the needle, and rotating the needle about an axis other than its own while inserted would be injurious to the patient.

(In fact there is an issue of whether the Blair system would work at all since, with the angled needle, advancing the cartridge 3 axially and not parallel to the needle while poking the needle through the plug 4 would put considerable lateral stress on the needle, arguably bending or breaking the needle or tearing the plug 4.)

Basically, Blair represents a system used in a totally different manner and the differences in structure - lack of a one-piece bow- or C-shaped bridge and of a grip part symmetrical to the needle axis for instance - clearly relate to structural differences that result in a different use so that it would in no way be obvious to alter Blair and make it conform to the instant invention.

# CONCLUSION

The instant invention as defined in the claims is clearly allowable over Blair §103. The new-matter rejections are based on the incorrect premise that the drawing is not part of the disclosure. Notice to that effect is earnestly solicited.

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Enclosure:

Appeal fee by EFS

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## VIII. CLAIM APPENDIX

- 1. A blood-collecting device for newborn babies and infants, the device comprising:
- a cannula extending along an axis and having at one axial end a blood inlet and at an opposite axial end a blood outlet;
  - a one-piece bow-shaped bridge element having a front end in which the cannula is fixed and a rear end through which the axis passes and defining with the front end a free space, the cannula outlet being exposed between the front and rear ends in the free space and the inlet being outside the free space; and
- a grip part centered on the axis and fixed on the rear end of the bridge element rearward of the rear end and outside the free space.
- 3. The device defined in claim 1 wherein the bridge element is C-shaped.
- 5. The device defined in claim 1 wherein the handle has an outer surface substantially symmetrical to the axis.

# IX. EVIDENCE APPENDIX

None.

# X. RELATED PROCEEDINGS APPENDIX

None.